

REMARKS

Claims 33-51 are pending in this application. Claim 1-16 were canceled previously. Claims 17-24 and 26-32 were withdrawn previously. Claim 25 was canceled in this reply. Claims 33, 36, 45, and 46 have been amended. Support for the amendments to the claims can be found throughout the specification and particularly in Figure 2 and on page 25, lines 20-33 of the as-filed specification, for example. No new matter has been added.

In the final office action dated January 15, 2009:

- 1) Claims 38 and 44-46 were determined to be allowable if rewritten into independent form and if the rejections under §112 are addressed;
- 2) Claims 33-37, 39, 42, 43, and 47 were rejected under 35 U.S.C. §102; and
- 3) Claims 40, 41, and 48-51 were rejected under 35 U.S.C. §103.

Withdraw of all currently applied rejections is respectfully requested for at least the reasons set forth below.

Allowable Subject Matter

Applicants appreciate that dependent claims 38 and 44-46 would be allowable if the rejections of those claims under §112 are addressed and the claims were rewritten into independent form to include the limitations of the base claim and any intervening claims.

Applicants believe that, in light of the arguments set forth below regarding the §112 and §102 rejections of the independent claim 33, all pending claims are patentable and allowance of all pending claims is respectfully requested.

Prior Art Claim Rejections

Claims 33, 36, and 42 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,223,365 (Freiherr Von Der Goltz, hereinafter "Freiherr").

Claims 33-35, 37, 39, and 47 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,494,639 (Grzegorzewski).

Applicants respectfully traverse these rejections.

The office action suggests that Grzegorzewski anticipates claim 33. Specifically, the office action contends that Grzegorzewski's piezoelectric element 8 is *a signal driver in communication with the transducer element, the signal driver applying a signal to the transducer element, and the signal driver varying a value of the signal*. With all due respect to the contentions in the office action, Applicants assert that Grzegorzewski's piezoelectric element 8 is not a signal driver.

A piezoelectric device, such as Grzegorzewski's element 8, may generate an electric potential in response to mechanical stress. However, a piezoelectric device does *not drive a signal*. As disclosed in the specification, embodiments contemplate a signal processor that comprises a system of accompanying electrical oscillatory circuits in which resonant transducer structures *control the oscillation frequency, phase, and the amplitude*. Thus, the signal processing section is capable of acting as a signal driver *to excite the transducer into appropriate vibrational modes* over a range of frequencies, phases and amplitudes in a controlled and predetermined manner. (See page 21, lines 24-33 and page 23, line 28 to page 24, line 22 of the as-filed specification, for example).

Grzegorzewski's piezoelectric element 8 is not a signal driver. Grzegorzewski's piezoelectric element 8 functions merely as a transducer. Grzegorzewski's piezoelectric element 8 transducer converts the vibrations created from a reaction of a test fluid with a reaction component in chamber 7 into a signal that is transmitted through the electrodes 14. Grzegorzewski's piezoelectric element 8 is not *controlling* the frequency, phase or amplitude of the signal to the electrodes 14. The frequency, phase and amplitude of the electric signal are an uncontrolled function of the reaction in the chamber 7. Grzegorzewski's electrodes 14 are *not being excited into appropriate vibrational modes*. Grzegorzewski's piezoelectric element 8, unlike a signal driver, is merely slavishly converting the vibrations created from the reaction in the chamber 7 into an electric potential. The electric potential is then transmitted through the electrodes 14 to an oscillator circuit 51. (See the Abstract and column 4, lines 22-62 and column 6, lines 3-20 of *Grzegorzewski*).

Therefore, Grzegorzewski does not disclose or suggest a signal driver in communication with a transducer element, where the signal driver applies a signal to the transducer element and varies a value of the signal. Accordingly, Applicants respectfully

request that the §102(b) rejection of claim 33 over Grzegorzewski be reconsidered and withdrawn.

Applicant believes that the dependent claims 34-35, 37, 39, 43, and 47 are patentable for at least the reason that the dependent claims depend from a patentable base claim and recite further patentable elements. Accordingly, Applicants respectfully request that the §102(b) rejections of claims 33-35, 37, 39, 43, and 47 be reconsidered and withdrawn.

On pages 2 and 3, the office action restates the previous rationale for the §102(e) rejection of claim 33 based on Freiherr. Specifically, the office action restates that Freiherr's elements 9 and 18 disclose a signal processor in connection with the transducer for determining a blood characteristic from the blood's response to the varying signal. The office action contends that Freiherr's elements 9 and 18 work in cooperation to determine changes in the blood characteristics based on the measured pressure in the chamber 3.

With all due respect to the contentions in the office action, Applicants continue to respectfully disagree because Freiherr's elements 9 and 18 are not a signal processor that determines the hemostasis functions of the blood *as a function of the blood's response to a signal*. Although the controller 18 may detect the varying pressure of the chamber 3 as measured by the gauge 9, the varying pressure is merely the response of the blood to the piston's 4 effect. Neither the gauge 9, nor the controller 18, are determining any characteristics of the blood *as a function of the measured pressure*, where the change in pressure is the blood's response to the signal from the controller 18 that varies the position of the piston 4.

Freiherr determines the hemostasis functions of whole blood or plasma. (*Freiherr* - Abstract). Freiherr's Figures 25-29 show examples of the hemostasis functions of the blood or plasma sample that are determined as a result of measurements taken. In operation, Freiherr discloses that the controller 18 controls the drive of motor 17, which in turn controls the motion of piston 4. The manipulation of piston 4 affects the pressure of the sample in the pressure gauge chamber 3. The pressure gauge 9 is connected to the chamber 3 to measure the pressure of chamber 3. The pressure gauge 9 is also connected to the controller 18 so that the controller 18 can control the movement of piston 4 (through motor 17) according to the pressure measured by pressure gauge 9. (*Freiherr* column 10, lines 11-46).

While the controller 18 measures the change in pressure in chamber 3 via the pressure gauge 9, the controller 18 does **not** determine a characteristic (hemostasis function) of the blood or plasma sample **as a function of that measured pressure change**. Freiherr does **not** disclose or suggest that the controller 18 is capable of the analysis required to determine the hemostasis functions of the blood or plasma as those functions are disclosed in Freiherr's Figures 25-29. Further, Freiherr does **not** disclose or suggest that the controller 18 has the capability to measure the other variables required to determine the hemostasis functions such as the volume in the cylinder 25 or the volumetric flow through the reaction device 39 after a certain predetermined time has elapsed. (*Freiherr* column 6, lines 57-60).

Thus, Freiherr's pressure gauge 9 and the controller 18 cannot determine the hemostasis function of the blood or plasma. Further, Freiherr does not disclose or suggest that the controller 18 and/or gauge 9 determines any characteristics of the blood **as function** of the blood's response to the signal that moves the piston 4. Freiherr only discloses that the controller 18 and/or gauge 9 determines the blood's response to the moving piston 4. At most, the pressure measured by the gauge 9 is an indication of the response of the blood to the moving piston 4. In other words, the pressure measured by the gauge 9 **is the blood's response** to the moving piston 4. The pressure measured by the gauge 9 cannot be interpreted **as a function of the response of the blood to the moving piston 4**. Such an interpretation is not logical as it would require the measured pressure in chamber 3 to be considered to be a function of itself. Freiherr is disclosing no such thing. Instead, Freiherr discloses the determination of the hemostasis functions of the blood based at least in part on the blood's pressure response to the moving piston 4. However, Freiherr does not disclose or suggest that the controller 18 or the gauge 9 determines the hemostasis functions. Therefore, Freiherr does **not** disclose or suggest a signal processor that determines a characteristic of the blood **as a function of a response of the blood to a signal**.

Accordingly, Applicants respectfully request that the §102(e) rejection of claim 33 over Freiherr be reconsidered and withdrawn.

Applicant believes that the dependent claims 36 and 42 are patentable for at least the reason that the dependent claims depend from a patentable base claim and recite further patentable elements. Accordingly, Applicants respectfully request that the §102(e) rejections of claims 36 and 42 be reconsidered and withdrawn.

Claims 48-50 are rejected under 35 U.S.C. §103(a) as being unpatentable over Freiherr in view of U.S. Patent No. 6,673,622 (Jina).

Claims 48 and 51 are rejected under 35 U.S.C. §103(a) as being unpatentable over Freiherr in view of U.S. Patent Application Publication No. 2004/0072357 (Stiene).

Claim 41 is rejected under 35 U.S.C. §103(a) as being unpatentable over Freiherr.

Claim 40 is rejected under 35 U.S.C. §103(a) as being unpatentable over Grzegorzewski in view of U.S. Patent Application Publication No. 2004/0054283 (Corey).

Applicant believes that the dependent claims 40, 41, and 48-51 are patentable for at least the reason that the dependent claims depend from a patentable base claim and recite further patentable elements. Accordingly, Applicant respectfully requests that the §103(a) rejections of claims 40, 41, and 48-51 be reconsidered and withdrawn.

Claim Rejections Under 35 U.S.C. §112

Claims 33-51 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The office action does not formally restate the §112, second paragraph rejections. However, based on the office action's response to Applicants' previous arguments, Applicants believe that the office action intended to restate the previous §112 rejection. Specifically, the office action appears to contend that the phrase "biological sensing media" is not defined in the specification or claims and is also not present in the specification or in the as-filed claims. Applicants traverse this rejection.

Without prejudice or disclaimer of the subject matter of claim 33, claim 33 has been amended to recite a "biological substance." Support for the recitation of a biological substance can be found throughout the specification and, for example, on page 25, lines 20-33 of the as-filed specification. Accordingly, Applicants respectfully request that the §112 rejection of claims 33-51 be reconsideration and withdrawn.

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Conclusion

Insofar as the office action's rejections having been adequately addressed, Applicants believes that the current application, including claims 33-51, is in condition for allowance and such action is respectfully requested.

The Examiner is invited to call the Applicants' undersigned representative to discuss this application should the Examiner determine such a discussion would facilitate the application's allowance.

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